

Sunset Public Hearing Questions for
Controlled Substance Database Committee
Created by Section 53-10-303, *Tennessee Code Annotated*
(Sunset Termination June 2023)

Enabling Statute, Purpose, and Rules and Regulations

1. Please provide a brief introduction to the committee including information about its purpose, statutory duties, staff, and administrative attachment.

The Controlled Substance Monitoring Database Committee (“committee”) was established pursuant to the Controlled Substance Monitoring Act of 2002. The committee consists of nine licensed healthcare professionals who represent their respective licensure boards—medical examiners, osteopathic examination, dentistry, podiatric medical examiners, optometry, veterinary medical examiners, nursing, physician assistants, and pharmacy—and two consumer members who represent the general public on the board of pharmacy and board of medical examiners. The committee advises the Commissioner of Health (“commissioner”) on any rulemaking commenced pursuant to Tenn. Code Ann. §§ 53-10-301 *et seq.* and may make formal recommendations to the commissioner.

2. Section 53-10-303(f), *Tennessee Code Annotated*, grants the commissioner authority to promulgate rules and Section 53-10-303(g), *Tennessee Code Annotated*, states the committee shall advise the commissioner with respect to any contemplated rulemaking under the provisions of this statute and make formal recommendations to the commissioner. If rules have been promulgated, please cite the reference. Did the committee make formal recommendations to the commissioner during the rule promulgation process?

The commissioner recently completed the rulemaking process for the Commissioner’s Controlled Substance Monitoring Database rules and Tennessee Board of Pharmacy Controlled Substance Monitoring Database rules, Tenn. Comp. R. & Regs. 1145-01 and 1140-11, respectively. The committee formally recommended that the commissioner promulgate and adopt these rules which became effective on January 26, 2022.

Committee Organization

3. Section 53-10-303, *Tennessee Code Annotated*, establishes membership requirements for the committee. Provide a list of current committee members. For each member, please indicate who appointed the member, statutory member representation, the beginning and the end of the member’s term, and whether the member is serving a consecutive term.

All members of the committee are appointed by their respective boards.

| Member | Board | Term |
|---------------------------|--------------------|----------------|
| Bhekumuzi Khumalo, D.P.M. | Board of Podiatry | 2019 – Present |
| Robert Caldwell, D.M.D. | Board of Dentistry | 2021 – Present |

| | | |
|------------------------------|--|----------------|
| Melanie Blake, MD | Board of Medical Examiners | 2018 – Present |
| Shant H. Garabedian, D.O. | Board of Osteopathy | 2018 – Present |
| Adam Rodgers, Pharm.D. | Board of Pharmacy | 2019 – Present |
| Robert White, PA | Committee on Physician Assistants | 2022 |
| Montgomery McInturff, D.V.M. | Board of Veterinary Medical Examiners | 2022 |
| Amber Wyatt, APRN | Board of Nursing | 2021 - Present |
| Robert Ellis | Public Member Board of Medical Examiners | 2018 - Present |
| Kurt Steele, O.D. | Board of Optometry | 2022 |
| Jake Bynum | Public Member Board of Pharmacy | 2021-Present |

4. Are there any vacancies on the committee? If so, please indicate how long the position has been vacant and explain steps that have been taken to fill any vacancies.

There are no current vacancies on the committee.

5. How many times did the committee meet in each of the last two fiscal years and to date in fiscal year 2022? How many members were present at each meeting? Please note meetings where the committee did not have a quorum.

The committee met three times in fiscal year 2020 and three times in fiscal year 2021. June 21, 2022, will be the third meeting of the committee for fiscal year 2022.

| Meeting Date | Fiscal Year | Committee Members Present | Quorum |
|---------------------|--------------------|----------------------------------|---------------|
| October 8, 2019 | FY2020 | 8 | Yes |
| February 3, 2020 | FY2020 | 9 | Yes |
| June 23, 2020 | FY2020 | 9 | Yes |
| October 6, 2020 | FY2021 | 9 | Yes |
| February 2, 2021 | FY2021 | 10 | Yes |
| June 22, 2021 | FY2021 | 8 | Yes |
| October 12, 2021 | FY2022 | 10 | Yes |
| February 15, 2022 | FY2022 | 7 | Yes |

Financial Information

6. What were the committee's revenues and expenditures for the last two fiscal years and to date in fiscal year 2022? Does the committee carry a reserve balance? If costs of the committee are allocated back to the boards that have prescriptive authority, please provide relevant information about this process and any associated costs.

The committee does not collect any fees. As a result, the committee does not have any revenues. At fiscal year-end, the cost of the committee is allocated to the Dental, Medical, Nursing, Optometry, Osteopathy, Podiatry, Veterinary, and Physician Assistant boards based on the percentage of licensees with prescriptive authority and the Pharmacy board based on the percentage of licensees.

For fiscal year 2020, the committee's total expenditures allocated to above boards were \$1,267,534.35.

For fiscal year 2021, the committee's total expenditures allocated to above boards were \$1,469,595.26.

As of December 31, 2021, the committee's total expenditures allocated to above boards were \$709,654.90.

The committee does not have legislative authority to maintain a reserve balance.

7. What per diem or travel reimbursements do committee members receive? How much was paid to committee members in each of the last two fiscal years and to date in fiscal year 2022?

Board members are paid a per diem for each meeting according to their respective board's rules. Travel reimbursements are paid by each member's board according to the Department of Finance and Administration's Comprehensive Travel Regulations. The per diem and travel amounts for each Board member listed below represents the amounts paid from July 1, 2019, through December 31, 2021, for their work with CSMD and their regular board duties.

| Member Name | Board Representing | FY20-Per Diem Total | FY20-Travel Reimbursement Total | FY21-Per Diem Total | FY21-Travel Reimbursement Total |
|--------------------|------------------------------|----------------------------|--|----------------------------|--|
| Melanie Blake | Medical Examiners | \$1,200.00 | \$2,420.22 | \$700.00 | \$0.00 |
| Mark Young | Nursing | \$1,150.00 | \$0.00 | \$400.00 | \$0.00 |
| Brett Reeves | Physician Assistants | \$700.00 | \$438.04 | \$500.00 | \$0.00 |
| Shant Garabedian | Osteopathy | \$500.00 | \$850.83 | \$500.00 | \$0.00 |
| Jake Bynum | Pharmacy | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Robert Simpson | Veterinary Medical Examiners | \$600.00 | \$4,679.60 | \$800.00 | \$0.00 |
| Robert Ellis | Medical Examiners | \$1,500.00 | \$3,715.98 | \$2,500.00 | \$1,068.19 |
| Adam Rodgers | Pharmacy | \$900.00 | \$851.56 | \$800.00 | \$13.16 |
| Amber Wyatt | Nursing | \$600.00 | \$1,476.66 | \$900.00 | \$438.76 |

| | | | | | |
|----------------------|------------------------------|------------|----------|------------|----------|
| Thomas Williams | Dentistry | \$400.00 | \$59.22 | \$200.00 | \$0.00 |
| Tonya Reynoldson | Optometry | \$300.00 | \$225.60 | \$300.00 | \$0.00 |
| Robert Caldwell | Dentistry | \$1,500.00 | \$211.50 | \$6,800.00 | \$569.17 |
| Bhekumuzi Khumalo | Podiatry | \$100.00 | \$0.00 | \$600.00 | \$0.00 |
| Montgomery McInturff | Veterinary Medical Examiners | \$0.00 | \$0.00 | \$400.00 | \$0.00 |
| Kurt Steele | Optometry | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Robert White | Physician Assistants | \$0.00 | \$0.00 | \$0.00 | \$0.00 |

| Member Name | Board Representing | FY22-Per Diem Total as of 12/31/21 | FY22-Travel Reimbursement Total as of 12/31/21 |
|----------------------|------------------------------|---|---|
| Melanie Blake | Medical Examiners | \$1,000.00 | \$2,504.10 |
| Mark Young | Nursing | \$0.00 | \$0.00 |
| Brett Reeves | Physician Assistants | \$200.00 | \$90.24 |
| Shant Garabedian | Osteopathy | \$200.00 | \$349.68 |
| Jake Bynum | Pharmacy | \$700.00 | \$1,200.88 |
| Robert Simpson | Veterinary Medical Examiners | \$100.00 | \$1,523.48 |
| Robert Ellis | Medical Examiners | \$1,400.00 | \$2,156.14 |
| Adam Rodgers | Pharmacy | \$800.00 | \$65.80 |
| Amber Wyatt | Nursing | \$500.00 | \$937.63 |
| Thomas Williams | Dentistry | \$0.00 | \$0.00 |
| Tonya Reynoldson | Optometry | \$400.00 | \$150.40 |
| Robert Caldwell | Dentistry | \$1,300.00 | \$338.40 |
| Bhekumuzi Khumalo | Podiatry | \$0.00 | \$0.00 |
| Montgomery McInturff | Veterinary Medical Examiners | \$100.00 | \$33.84 |
| Kurt Steele | Optometry | \$0.00 | \$0.00 |
| Robert White | Physician Assistants | \$0.00 | \$0.00 |

8. Does the committee collect fees? If yes, provide relevant information about fees collected. Indicate whether fees were established through rule or through state law.

The Committee does not collect any fees.

Sunshine Law, Public Meetings, and Conflict of Interest Policies

9. Section 53-10-303(e), *Tennessee Code Annotated*, states that except under specific conditions, the committee is subject to Sunshine law requirements (Section 8-44-101 et seq., *Tennessee Code Annotated*) for public notice of meetings, prompt and full recording of minutes, and public access to minutes? If so, what procedures does the committee have for informing the public of meetings and making minutes available to the public? How many meetings has the committee held in the last two fiscal years and to date in fiscal year 2022 which fall within the limited exemption to the Sunshine law?

Yes. The committee is subject to Sunshine law requirements of Tenn. Code Ann. 8-44-101. The public meeting notice is posted to the Department's website thirty (30) days prior to the meeting as well as posting the information on the Public Participation Calendar. Each meeting is recorded and streamed live for public viewing. The committee's assigned administrative staff attends all meetings and ensures recording is initiated. The minutes are then prepared for review and ratification by the committee at its next regularly scheduled meeting. After the minutes are ratified, they are then placed on the committee's website. All portions of committee meetings held within the last two fiscal years and to date in fiscal year 2022 have followed the Sunshine law requirements, with no exemptions required.

10. Does the committee allow public comment at meetings? Is prior notice required for public comments? If public comment is not allowed, how does the committee obtain feedback from the public and those they regulate?

Committee meetings are conducted in full view of the public pursuant to a sunshine notice which provides information for the location of the meeting, a link to remotely view live streaming of the meeting and notice of agenda items. The meeting is guided by the published agenda. The committee will recognize members of the public who request to be heard on a matter properly noticed before the committee.

Additionally, all health-related boards have instituted a sign-in sheet procedure at the meeting location that permits members of the public to make time-limited comments on matters properly noticed and before the committee for consideration. Discussion of matters not receiving proper notice would violate the sunshine laws of Tennessee. Therefore, if a member of the public has a topic or comment that requires discussion, they are asked to make the request known to the committee administrator or director in advance to have the matter placed on the sunshine notice. The committee could also accept and review letters as another means of addressing questions/concerns raised by the public and stakeholders.

A video recording of the meeting is placed on the committee's website within 24-48 hours of the meeting and is also available on the Department's web site for approximately one month following the meeting. An audio recording of the meeting is also available upon request.

11. What policies and procedures are in place to address potential conflicts of interest of committee members, employees, or other state employees who work with the committee. If the committee has a conflict-of-interest policy, please provide a copy.

Each member of the CSMD committee follows the conflict-of-interest policy of their respective board. Their respective boards review the Department of Health's Conflict of Interest Policy and are required to sign a Conflict-of-Interest Statement upon appointment, or as soon as practical, and annually thereafter. State employees who work with the committee are required to sign a new conflict of interest statement annually.

Oversight Responsibilities

12. What actions has the committee taken in the last two years and to date in fiscal year 2022 under the provisions of Section 53-10-303(h) to identify unusual patterns of prescribing and refer the healthcare practitioner to the appropriate licensing board?

The committee can make referrals to Office of Investigations (OIV) pursuant to Tenn. Code Ann. § 53-10-303(h)(2). However, it cannot readily be determined how many matters have been referred to OIV during the period at issue because OIV broadly categorizes such referrals as complaints from the health-related boards division, not specifically CSMD complaints.

13. Does the committee maintain reciprocal agreements with other states to recognize associated professions who are licensed under the laws of other states such that these individuals may practice in Tennessee?

The committee is not a licensing board so therefore does not maintain any reciprocal agreements with other states to recognize associated professions who are licensed under the laws of other states so that they may practice in Tennessee

14. Please provide a list of all committee or database contracts, with information about each contractor, the services provided, the length of the contract, and the amount of the contract.

The committee or database holds the following contracts:

- Bamboo Health (formerly known as Appriss Inc.)
 - Bamboo Health is the vendor for data collection and the vendor for the database, which are two separate applications. Bamboo Health is also a vendor for Gateway, an electronic health record integration tool. There is a wide array of services provided by Bamboo Health that include requested enhancements to data collection and CSMD, support of OTECH, PMPi, Gateway Service, and RxCheck Connection.

- The initial contract was from January 1, 2019 to December 31, 2021 but subsequent amendments have extended the contract through December 31, 2022. There is a current amendment in progress that would extend to December 31, 2023 but the final amount of the amendment is not known at the time of this questionnaire. The current contract and amendments from January 1, 2019 to December 31, 2022 totals \$6,295,559.21.
- National Association of Board of Pharmacy (NABP)
 - NABP provides the Prescription Monitoring Program InterConnect (PMPi). PMPi which is utilized to provide the CSMD program with access to out-of-state prescription drug monitoring program (PDMP) information to further support the lawful purpose of such programs.
 - The contract is from September 16, 2021 to September 15, 2026. This is a no cost contract which involves no monetary obligations between parties.
- Integrated Justice Information Systems Institute, Inc. (IJIS)
 - IJIS provides support of the RxCheck System, a portal through which authorized users from the State and Third Party States may request access to information regarding the other party's State Prescription Data. RxCheck was developed and is operated under the guidance of U.S. Department of Justice, Office of Justice Program's Bureau of Justice Assistance.
 - This Memorandum of Understanding was executed on August 14, 2019 and is renewed automatically each year if not terminated earlier by either party. There is no cost associated with this memorandum of understanding.

Reports, Major Accomplishments, and Proposed Legislative Changes

15. What reports does the committee prepare concerning its activities, operations, and accomplishments? Who receives copies of these reports? Please provide a link to any such reports issued in the last two fiscal years.

As required in Tenn. Code Ann. § 53-10-309, the committee files an annual report by March 1 of each year to the Chair of the Health and Welfare Committee of the Senate and to the Chair of the Health Committee of the House of Representatives. This report includes an analysis of the individuals or entities that access the database and the security measures taken to ensure that only authorized persons or entities access the database, as well as key findings and considerations. The Controlled Substance Monitoring Database Report to Tennessee General Assembly is publicly available and can be found on the [Tennessee Department of Health Publications](#) page.

16. What were the committee's major accomplishments during the last two fiscal years and to date in fiscal year 2022?

The committee successfully received approval for funds to pay for two years of Gateway Electronic Health Record, which allows for integration into current workflows for health care providers. The committee has also been successful in implementing RxCheck

Interstate Data Sharing. The Prescription Monitoring Program InterConnect (PMPi) is now being shared with over 30 states.

17. What challenges has the committee addressed in the last two fiscal years and to date in fiscal year 2022?

The committee is currently reliant on funding from boards that license those with prescriptive authority and the Board of Pharmacy. The committee continues to operate successfully within these constraints and adapts as needed to the funding constraints that this can cause.

The committee has successfully recommended that the commissioner rules for the CSMD be adopted and are now effective.

18. Please describe any items related to the committee that require legislative attention and your proposed legislative changes.

There are no items related to the committee that require legislative attention at this time.

19. Should the committee be continued? To what extent and in what ways would the absence of the committee affect the public welfare of the citizens of Tennessee?

Yes. While there are many state and federal strategies that have led to a decrease in the following data points, the committee is instrumental in providing guidance to the CSMD program on the utilization and interpretation of data that has led to investigations and regulatory changes. Without this direction, there could be a protentional increase in Morphine Milligram Equivalents (MME), doctor and pharmacy shopping, opioid prescriptions for pain, Neonatal Abstinence Syndrome (NAS), controlled substance prescribing and dispensing, fatal and non-fatal overdoses, drug to drug interactions, and concomitant therapy.

20. Please identify the appropriate agency representative or representatives possessing substantial knowledge and understanding of the responses provided to the sunset review questions.

Jennifer Putnam, Assistant Commissioner, Health Licensure and Regulation

Elizabeth Foy, Assistant Commissioner, Legislative Affairs

Alicia Grice, Fiscal Director, Health Licensure and Regulation

Lucy Shell, Executive Director, Tennessee Board of Pharmacy

Andrea Miller, Interim Director, Controlled Substance Monitoring Database

Tracy Bacchus, Administrative Assistant, Controlled Substance Monitoring Database

Sean Boling, Statistical Programmer Specialist, Controlled Substance Monitoring Database

Debora Sanford, Clinical Application Coordinator, Health Licensure and Regulation
Jae Lim, Senior Associate General Counsel

21. Please identify the appropriate agency representative or representatives who will respond to the questions at the scheduled sunset hearing.

Jennifer Putnam, Assistant Commissioner, Health Licensure and Regulation
Elizabeth Foy, Assistant Commissioner, Legislative Affairs
Alicia Grice, Fiscal Director, Health Licensure and Regulation
Lucy Shell, Executive Director, Tennessee Board of Pharmacy
Jae Lim, Senior Associate General Counsel

22. Please provide the office address, telephone number, and email address of the agency representative or representatives who will respond to the questions at the scheduled sunset hearing.

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